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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,649

10/27/2003

Hanson S. Gifford III

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

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02/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/695,649	<b>Applicant(s)</b> GIFFORD ET AL.	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-14 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14, 18-20 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/2009 has been entered.

### ***Claim Objections***

2. Claim 11 is objected to because of the following informalities: "the gap" of line 7 is lacking antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 11, 14, 18, 19, and 22 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shapland et al. (US 6,425,856, hereinafter "Shapland").

7. In regards to claims 11 and 14, Shapland discloses the essential features of the claimed invention including placing a band having a first end and second end around a beating heart (Figs. 9A and 9B; the two "ends" of the band are two arbitrary points around the circumference of the band); and drawing the first and second ends of the band by a supporting spring member under tension (col. 12, lines 21-35; the "supporting spring member" is the length of the device that connects the two arbitrary ends of the band in the opposite direction from the band) that spans the gap and has a biodegradable element which delays the ends of the band from drawing together, and wherein the band leaves a gap between the first and second ends after the ends have been drawn together (col. 12, lines 21-35; Figs. 9A and 9B; since the relaxed "spring

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member” still had some length, this leaves a “gap” between the two arbitrary points).

Please note that the claim language does not require the "band" portion and the "spring" portion to be different materials. Since Shapland's invention comprises a device that is both a band and a spring, the Examiner takes the position that any two arbitrary locations around the device can constitute the "ends" of the band. In the alternative, Shapland's embodiment in column 12, lines 21-35 discloses the essential features of the claimed invention except for a band having a first and second ends with the disclosed supporting spring member spanning the gap. However, Shapland also teaches providing a cardiac constraint device with a band having a first and second ends with a supporting spring member spanning the gap (col. 16, lines 29-48; Fig. 10) and that “other adjustment systems or mechanisms may include combinations of the above described mechanisms” (col. 12, lines 36-38) to provide the predictable results of defining a volume that approximates the maximum cardiac volume of a healthy heart (col. 16, lines 35-38), but firstly sized for initial placement on the heart (col. 12, lines 27-29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shapland's embodiment described in column 12 with the embodiment described in column 16 to provide the predictable results of defining a volume that approximates the maximum cardiac volume of a healthy heart, but firstly sized for initial placement on the heart.

**8.** In regards to claims 18 and 19, the band is introduced to the heart and at least a portion is below the AV groove (Figs. 3A, 4A, and 10).

**9.** In regards to claim 22, the device treats mitral regurgitation (col. 6, lines 12-25).

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**10.** Claim 20 is rejected under 35 U.S.C. 103(a) as obvious over Shapland.

Shapland discloses the essential features of the claimed invention, but does not expressly disclose implanting with a subxiphoid approach. It is well known in the art to implant similar devices via a subxiphoid approach to provide the predictable results of implanting the device without the need to spread the chest. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shapland's invention by implanting via a subxiphoid approach to provide the predictable results of implanting the device without the need to spread the chest.

**11.** Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapland in view of McCarthy et al. (US 6,406,420, hereinafter "McCarthy").

Shapland discloses the essential features of the claimed invention, including a band adhered to heart tissue (col. 12, line 60 to col. 13, line 18), but does not expressly disclose ends located on and adhered to opposite sides of an infarcted region.

McCarthy teaches a band device comprising ends located on opposite sides of an infarcted region (col. 6, ll. 39-63) to provide the predictable results of promoting reverse remodeling of this compromised tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Krueger's invention by providing ends located on opposite sides of an infarcted region to provide the predictable results of promoting reverse remodeling of this compromised tissue.

***Response to Arguments***

**12.** Applicant's arguments with respect to claims 11-14, 18-20, and 22 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/

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Examiner, Art Unit 3762

/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762